CLAIMS

- 1. A method for determining the distribution of at least one outcome resulting from the administration of a compound to at least one human, comprising the steps of:
- (a) using non-linear mixed effects modeling to determine a value and a standard error for each of a plurality of allometric parameters;
- (b) inputting said value and said standard error of at least one of said plurality of allometric parameters into a stochastic pharmacokinetic model, wherein said allometric parameter is designated as a random variable; and
- (c) using said stochastic pharmacokinetic model to computationally simulate administration of said compound to said human to produce said distribution of said outcome.
- 2. The method according to claim 1, wherein at each of said allometric parameter is designated as a random variable with a specified probability density in said stochastic pharmacokinetic model.
- 3. The method according to claim 2, wherein said random variable has a mean value equal to the value of said allometric parameter, and a standard deviation equal to said standard error of said allometric parameter.
- 4. The method according to claim 3, wherein said specified probability density corresponds to either a normal distribution or a lognormal distribution.

5. The method according to claim 1, wherein said outcome is selected from AUC, Cmax, C24, Cavg, Cmin, or a pharmacodynamic response.
6. The method according to claim 5, wherein said pharmacokinetic response is selected from AUC, or Cmax.

- 7. The method according to claim 5, wherein said pharmacodynamic response is selected from inhibition or stimulation of a biological target.
- 8. The method according to claim 1, wherein said allometric parameter correspond to an allometically scaled pharmacokinetic parameter selected from clearance, volume distribution, or inter-compartmental volume.
- 9. The method according to claim 8, wherein said pharmacokinetic parameter is CL or V.
- 10. A method for selecting an optimal dose range of a compound for administration for the first time to a human, comprising the steps of:
- (a) selecting one or more outcomes and distribution thereof derived according to the method of claim 1;
- (b) based on said distribution selecting a minimum dose level corresponding to a desired level of safety or a desired minimum pharmacological effect; and
- (c) based on said distribution selecting a maximum dose level corresponding to a desired level of safety and a desired maximal pharmacological effect.

11. An optimal dose range of a compound for administration for the first time to a human, wherein said optimal dose range is selected according to claim 10.